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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98 D–0727]

Draft "Guidance for industry: interpretation of On-farm Feed Manufacturing and Mixing Operations"; Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Interpretation of On-farm Feed Manufacturing and Mixing Operations. " The draft guidance is intended to clarify the applicability of certain sections of the Animal Proteins Prohibited from Use in Animal Feed regulation to ruminant feeders. The agency is requesting comments on this draft guidance,

DATES: Submit written comments by *(insert date 60 days after date of publication in the* Federal Register.)

ADDRESSES: Submit written requests for single copies of this draft guidance to the Communications Staff (HFV–1 2), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pi., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rrn. 1061, Rockville, MD 20852. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the draft guidance.

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FOR FURTHER INFORMATION CONTACT: Gloria J. Dunnavan, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7500 Standish Pi., Rockville, MD 20855,301-594-1726, E-mail: gdunnava@bangate. fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

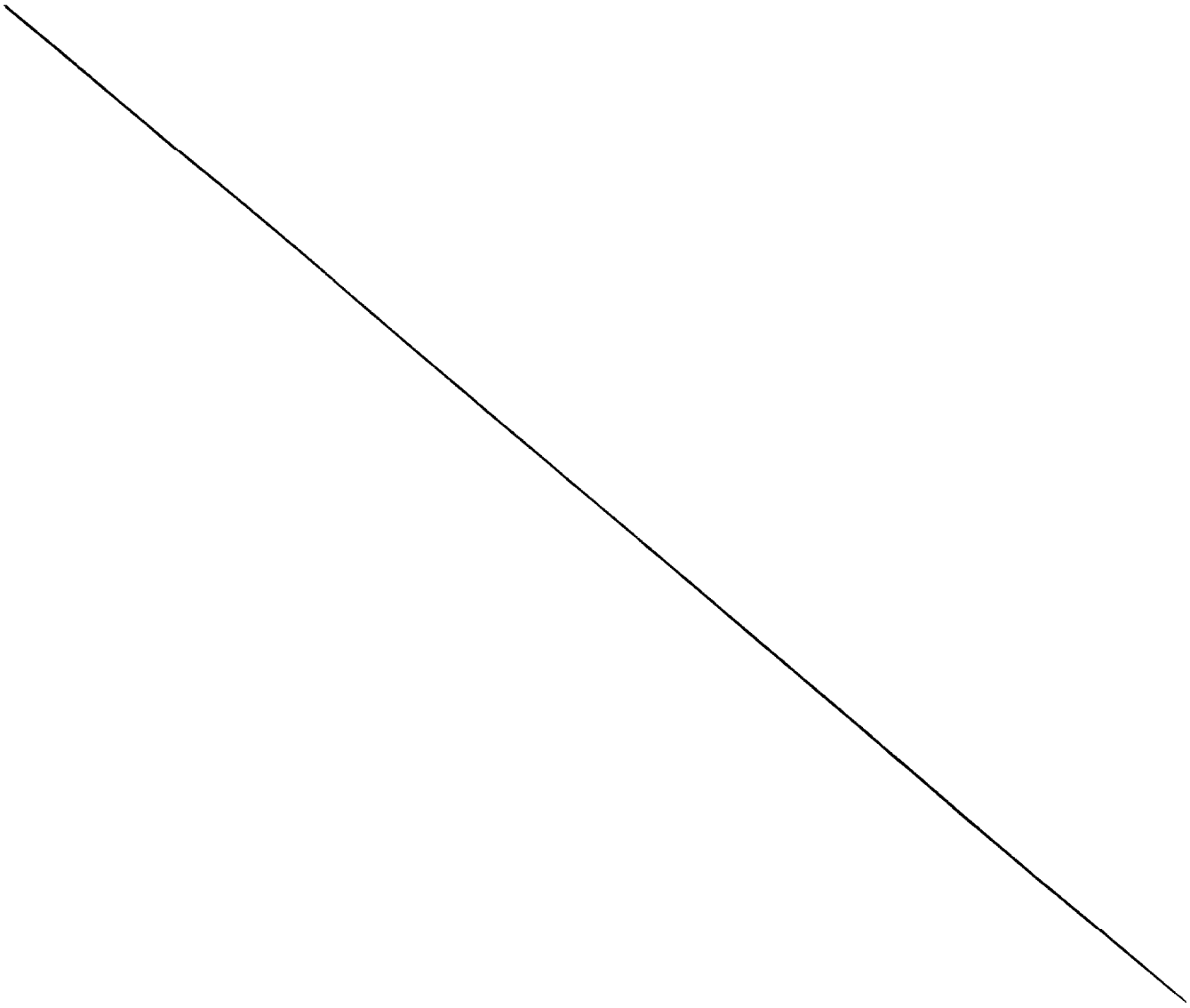
Section 589.2000 *Animal proteins prohibited from use in animal feed (21* CFR 589.2000) defines "feed manufacturer" to include "on-farm feed manufacturing and mixing operation." This draft guidance makes it clear that an operation that mixes, but does not manufacture feed onfarm is not considered a feed manufacturer by FDA. Rather such mixing operations are ruminant feeders. While all ruminant feeders are subject to the regulation, the regulation imposes significantly different requirements on ruminant feeders that are also "feed manufacturers. " For this reason, FDA finds it necessary to clarify the phrase "on-farm feed manufacturing and mixing operations. "

FDA believes that a ruminant producer who mixes total mixed rations (TMR's), a complete mix of the cow's daily diet, for the animals under the producer's control is not "manufacturing and mixing. " This draft guidance provides our rationale for this interpretation.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961,, February 27, 1997). This draft guidance is issued as a Level 1 guidance consistent with GGP's. If finalized, this document will represent current FDA thinking on on-farm feed manufacturing and mixing operations and their responsibilities under $589.2000. The guidance will not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternate approaches may be used if they satisfy the requirements of applicable statutes, regulations, or both.

II. Comments

Interested persons should submit written comments on or before (*insert date 60 days after date of publication in the* Federal Register), to the Dockets Management Branch (address above) regarding this draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the draft guidance using the World Wide Web (WWW). For WWW access, connect to CVM at ''http://www.fda.gov/cvm''.

Dated: September 8, 1998

September 8, 1998

William K. Hubbard
Associate Commissioner for Policy Coordination

[FR **Dec. 98-????** Filed ??-??-98; 8:45 am]

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